B1

2. (Twice Amended) An isolated nucleic acid molecule comprising a sequence that:

(a) encodes the amino acid sequence shown in SEQ ID NO: 2; and

(b) hybridizes under highly stringent conditions with wash conditions of 0.1xSSC/0.1%SDS at 68°C to the nucleotide sequence of SEQ ID NO: 1 or the complement thereof.

Please add new Claims 5-8 as follows:

5. (NEW) A recombinant expression vector comprising the isolated nucleic acid molecule of claim 3.

6. (NEW) A host cell comprising the recombinant expression vector of claim 5.

B2

7. (NEW) A recombinant expression vector comprising the isolated nucleic acid molecule of claim 4.

8. (NEW) A host cell comprising the recombinant expression vector of claim 7.

RESPONSE

I. Status of the Claims

Claim 2 has been amended. Claims 5-8 have been added. Applicants submit that Claims 5-8 are dependent claims that are properly classified into the same class and subclass and are therefore proper. Claims 1-8 are therefore presently pending in the case. For the convenience of the Examiner, a clean copy of the pending claims is attached hereto as **Exhibit A**. In compliance with 37 C.F.R. § 1.121(c)(1)(ii), a marked up copy of the original claims is attached hereto as **Exhibit B**.

II. Support for the Amended Claims

Claim 2 has been amended to further clarify the claim, and to recite highly stringent conditions. Amendment of Claim 2 finds support throughout the specification as originally filed, with particular support being found at page 4, lines 11-12.

Claim 5 has been added to specifically recite recombinant expression vectors comprising the isolated nucleic acid molecule of Claim 3. Support for this claim can be found throughout the specification and in claim 1 as originally filed, with particular support being found in at least at page 13, lines 4-10.

Claim 6 has been added to specifically recite host cells comprising the recombinant expression vectors of claim 5. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least at page 13, lines 10-16.

Claim 7 has been added to specifically recite recombinant expression vectors comprising the isolated nucleic acid molecule of Claim 4. Support for this claim can be found throughout the specification and in claim 1 as originally filed, with particular support being found in at least at page 13, lines 4-10.

Claim 8 has been added to specifically recite host cells comprising the recombinant expression vectors of claim 7. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least at page 13, lines 10-16.

As these amendments to claim 2 and new claims 5-8 are fully supported by the specification and claims as originally filed, they do not constitute new matter. Entry, therefore, is respectfully requested.

III. Rejection of Claims Under 35 U.S.C. § 101

The Action persists in rejecting claims 1-4 under 35 U.S.C. § 101, allegedly because the claimed invention lacks support by either a specific and substantial asserted utility or a well established utility. Applicants respectfully continue to traverse.

The Action quotes several articles, for example, one by Ji *et al.* ("Ji"; 1998, J. Biol. Chem. *273*:17299-17302) as teaching that structural homology alone is not a good predictor of function. But an exact quote from Ji, completely undermines this argument: "a substantial degree of amino acid homology is found between members of a particular subfamily, but comparisons between subfamilies

show significantly less or no similarity" (Ji at 17299, first paragraph, emphasis added). This quote suggests that homology with members of a G-protein coupled receptor is indicative that the particular sequence is in fact a member of that subfamily - the fact that there is little or no homology between subfamilies is completely irrelevant.

The Action also cites Yan *et al.* ("Yan"; 2000, Science 290:523-527) for the proposition that "even a two-amino acid substitution in a molecular structure of a protein can lead to total loss of a protein (*sic*) to bind a specific receptor" (Action at page 4). However, this paper cites only one example, two isoforms of the anhidrotic ectodermal dysplasia (EDA) gene, where a two amino acid change conforms one isoform (EDA-A1) into the second isoform (EDA-A2). However, while it is true that this amino acid change results in binding to different receptors, it is important to note that the different receptors bound by the two isoforms are in fact related (Yan at page 523). Furthermore, the EDA-A2 receptor was correctly identified as a member of the tumor necrosis factor receptor superfamily based solely on sequence similarity (Yan at page 523). Thus, Yan is hardly indicative of a high level of uncertainty in assigning function based on sequence, and thus also does not support the alleged lack of utility.

Rather, as set forth by the Federal Circuit, "(t)he threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip Inc. v. Orange Bang Inc.*, 51 USPQ2d 1700 (Fed. Cir. 1999) (citing *Brenner v. Manson*, 383 U.S. 519, 534 (1966)). Additionally, the Federal Circuit has stated that to violate § 101 the claimed invention "must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992), emphasis added. *Cross v. Iizuka* (224 USPQ 739 (Fed. Cir. 1985)) states "any utility of the claimed compounds is sufficient to satisfy 35 U.S.C. § 101". *Id* at 748, emphasis added. Indeed, the Federal Circuit recently emphatically confirmed that "anything under the sun that is made by man" is patentable *(State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 47 USPQ2d 1596, 1600 (Fed. Cir. 1998), citing the U.S. Supreme Court's decision in *Diamond vs. Chakrabarty*, 206 USPQ 193 (S.Ct. 1980)).

To summarize Applicants position, which is described in detail in instant application and Paper No. 11, Applicants have disclosed a CD20 and IgE receptor like protein and the polynucleotides encoding the same. Applicants have also provided "real world"evidence that CD20 and IgE receptor like protein are the target for human medical therapies. Applicants have also provided evidence that

others of skill in the art would also recognize the present invention to be a CD20 and IgE receptor like protein.

Applicants now present clear and convincing evidence that those of skill in the art have identified the present invention, and would therefore find our assertion that the present invention credible, as a CD20 and IgE receptor like protein. The sequences of the present invention are contained within molecules that have been identified and annotated by third party scientists, wholly unaffiliated with Applicants, as encoding CD20 or IgE receptor like molecules. For example (see Exhibits C and D): Accession No. AF2370907 identified as Homo sapiens MS4A5 protein mRNA and described in a peer reviewed publication entitled "Identification of a CD20-, FcepsilonRIbeta-, and HTm4-related gene family: sixteen new MS4A family members expressed in human and mouse" (Liang Y, Tedder TF, Genomics,2001 Mar 1;72(2):119-27); and Accession No. AB013103 identified as Homo sapiens mRNA for MS4A5 and described in a peer reviewed publication entitled "Identification of a new multigene four-transmembrane family (MS4A) related to CD20, HTm4 and beta subunit of the high-affinity IgE receptor" (Ishibashi,K., *et al.*, Gene 264 (1), 87-93, 2001). Applicants have thus provided clear and convincing evidence that those of skill in the art would find Applicants identification and utilities credible.

The Action argues (on page 5, lines 11-12) that " Without knowing biological function of the claimed molecule, would not know what to do with the claimed invention." In fact the biological function of the claimed invention has been disclosed, it is a CD20 or IgE receptor like molecule and has the biological functions know to those of skill in the art of CD20 or IgE receptor like molecules. Indeed, it is difficult to accept the given the propensity of knowledge surrounding CD20 or IgE receptor like molecules in published articles and books, issued patents and the like, that one of skill in the art would not know what to do with the claimed invention and would not readily recognize its utility.

Given these identifications and accompanying disclosures, the disclosure of the present invention, the wealth of published art, as well as issued U.S. Patents on the utility and use of CD20 and IgE receptor like proteins in, *inter alia*, signal transduction, allergies and asthma. Those of skill in the art would clearly recognize the utility of the present invention as well as be enabled to make and use the present invention without undue experimentation. Thus, the present invention clearly credible and well established utility.

The Examiner is, therefore, respectfully requested to withdraw the pending rejection of Claims 1-4 under 35 U.S.C. § 101.

IV. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

The Action rejects claims 1-4 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the claimed invention, as the invention allegedly is not supported by a specific, substantial, and credible utility or a well-established utility. Applicants respectfully traverse.

Applicants submit that as claims 1-4 have been shown to have a specific, substantial, credible and well established utility (see above) and that given the clear identification of the present invention as a CD20 and IgE receptor like protein and the related disclosures, the wealth of published art, as well as issued U.S. Patents on the utility and use of CD20 and IgE receptor like proteins and combined the disclosure of the present invention, those of skill in the art would clearly know how to make and use the present invention without undue experimentation. Applicants therefore respectfully request that the rejection of claims 1-4 under 35 U.S.C. § 112, first paragraph, be withdrawn.

V. Rejection of Claim 2 Under 35 U.S.C. § 112, Second Paragraph

The Action rejects Claim 2 as allegedly indefinite based on the use of phrase " highly stringent conditions". Although Applicants believe that this claim as originally filed sufficiently points out and distinctly claims the invention, in order to more rapidly progress the case to allowance, Applicants have amended Claim 2 to include specific wash conditions. Applicants respectfully submit that this rejection has thus been avoided by Applicant's amendment of Claim 2 to specify wash conditions. Accordingly, the Examiner is respectfully requested to withdraw the pending rejection of Claim 2 under 35 U.S.C. § 112, second paragraph.

VI. Conclusion

The present document is a full and complete response to the Action. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance, and such favorable action is respectfully requested. Should Examiner Li have any questions or comments, or

believe that certain amendments of the claims might serve to improve their clarity, a telephone call to the undersigned Applicants' representative is earnestly solicited.

This response is timely filed and Applicants believe no fees are due in connection with this response. However, should this be incorrect the Commissioner is authorized to charge any required fees or credit any overpayment to Deposit Account No. 50-0892.

Respectfully submitted,

July 12, 2002
Date

Lance K Ishimoto Reg. No. 41,866

LEXICON GENETICS INCORPORATED
(281) 863-3333

24231
PATENT TRADEMARK OFFICE

Exhibit A

Clean Version of The Pending Claims in U.S. Patent Application Ser. No. 09/735,712

1. (Amended) An isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1.

2. (Twice Amended) An isolated nucleic acid molecule comprising a sequence that:

(a) encodes the amino acid sequence shown in SEQ ID NO: 2; and

(b) hybridizes under highly stringent conditions with wash conditions of 0.1xSSC/0.1%SDS at 68°C to the nucleotide sequence of SEQ ID NO: 1 or the complement thereof.

3. An isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO: 2.

4. An isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO: 8.

5. (NEW) A recombinant expression vector comprising the isolated nucleic acid molecule of claim 3.

6. (NEW) A host cell comprising the recombinant expression vector of claim 5.

7. (NEW) A recombinant expression vector comprising the isolated nucleic acid molecule of claim 4.

8. (NEW) A host cell comprising the recombinant expression vector of claim 7.

Exhibit B

Marked Up Version of Amended Claims in U.S. Patent Application Ser. No. 09/735,712

1. (Amended) An isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1.

2. (Twice Amended) An isolated nucleic acid molecule comprising a nucleotide sequence that:

(a) encodes the amino acid sequence shown in SEQ ID NO:2; and

(b) hybridizes under highly stringent conditions with wash conditions of 0.1xSSC/0.1%SDS at 68°C to the nucleotide sequence of SEQ ID NO:1 or the complement thereof.

3. An isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO: 2.

4. An isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO:4.

5. (NEW) A recombinant expression vector comprising the isolated nucleic acid molecule of claim 3.

6. (NEW) A host cell comprising the recombinant expression vector of claim 5.

7. (NEW) A recombinant expression vector comprising the isolated nucleic acid molecule of claim 4.

8. (NEW) A host cell comprising the recombinant expression vector of claim 7.

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 FASTA searches a protein or DNA sequence data bank
 version 3.3t05 March 30, 2000
Please cite:
 W.R. Pearson & D.J. Lipman PNAS (1988) 85:2444-2448

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MapView, Related Sequences, OMIM, Protein, PubMed, Taxonomy, LinkOut

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Revised: October 24, 2001.

Jun 12 2002 10:51:26

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MapView, Related Sequences, OMIM, Protein, PubMed, Taxonomy, LinkOut

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  AUTHORS   Ishibashi,K.
  TITLE     Direct Submission
  JOURNAL   Submitted (20-APR-1998) Kenichi Ishibashi, Tokyo Medical and Dental
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 99.834% identity in 603 nt overlap (1-603:52-654)

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               400       410       420       430       440       450
hMEM_5 GGAATCATTCTCCTCACATTTGGTTTCATCCTAGATCAAAACTACATTTGTGGTTATTCT
       ::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::
gi|115 GGAATCATTCTCCTCACATTTGGTTTCATCCTAGATCAAAACTACATTTGTGGTTATTCT
              450       460       470       480       490       500

               460       470       480       490       500       510
hMEM_5 CACCAAAATAGTCAGTGTAAGGCTGTTACTGTCCTGTTCTTGGGAATTTTGATTACATTG
       ::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::
gi|115 CACCAAAATAGTCAGTGTAAGGCTGTTACTGTCCTGTTCTTGGGAATTTTGATTACATTG
              510       520       530       540       550       560

               520       530       540       550       560       570
hMEM_5 ATGACTTTCAGCATTATTGAATTATTCATTTCTCTGCCTTTCTCAATTTTGGGGTGCCAC
       ::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::
gi|115 ATGACTTTCAGCATTATTGAATTATTCATTTCTCTGCCTTTCTCAATTTTGGGGTGCCAC
              570       580       590       600       610       620

               580       590       600
hMEM_5 TCAGAGGATTGTGATTGTGAACAATGTTGTTGA
       ::::::::::::::::::::::::::::::::
gi|115 TCAGAGGATTGTGATTGTGAACAATGTTGTTGACTAGCACTGTGAGAATAAAGATGTGTT
              630       640       650       660       670       680

gi|115 AAAATATAAA
              690

>>gi|11559213|dbj|AB013103.1|AB013103 Homo sapiens mRNA   (691 nt)
rev-comp initn:  60 init1:  60 opt:  60
 76.190% identity in 21 nt overlap (464-444:652-672)

         490       480       470       460       450       440
hMEM_- CCCAAGAACAGGACAGTAACAGCCTTACACTGACTATTTTGGTGAGAATAACCACAAATG
                                        ::::::    ::::::::::
gi|115 TCAGAGGATTGTGATTGTGAACAATGTTGTTGACTAGCACTGTGAGAATAAAGATGTGTT
              630       640       650       660       670       680

         430       420       410       400       390       380
hMEM_- TAGTTTTGATCTAGGATGAAACCAAATGTGAGGAGAATGATTCCAGCTATTGCTCCCAGG

gi|115 AAAATATAAA
              690


603 residues in 1 query   sequences
691 residues in 1 library sequences
 Scomplib [version 3.3t05 March 30, 2000]
 start: Wed Jul 10 14:42:29 2002 done: Wed Jul 10 14:42:29 2002
 Scan time:  0.016 Display time:  0.034

Function used was FASTA
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ORIGIN
        1 gactgaagta ccaactaagt catctccttt caaattatca ccgacaccat catggattca
       61 agcaccgcac acagtccggt gtttctggta tttcctccag aaatcactgc ttcagaatat
      121 gagtccacag aactttcagc cacgaccttt tcaactcaaa gccccttgca aaaattattt
      181 gctagaaaaa tgaaaatctt agggactatc cagatcctgt ttggaattat gacctttct
      241 tttggagtta tcttcctttt cactttgtta aaaccatatc caaggtttcc ctttatattt
      301 ctttcaggat atccattctg gggctctgtt ttgttcatta attctggagc cttcctaatt
      361 gcagtgaaaa gaaaaaccac agaaactctg ataatattga gccgaataat gaattttctt
      421 agtgccctgg gagcaatagc tggaatcatt ctcctcacat ttggtttcat cctagatcaa
      481 aactacattt gtggttattc tcaccaaaat agtcagtgta aggctgttac tgtcctgttc
      541 ttgggaattt tgattacatt gatgactttc agcattattg aattattcat ttctctgcct
      601 ttctcaattt tggggtgcca ctcagaggat tgtgattgtg aacaatgttg ttgactagca
      661 ctgtgagaat aaagatgtgt taaaatataa a
//
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Revised: October 24, 2001.